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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,755	07/24/2003	Richard Adam Janeczko	53436/88	9997

27871 7590 03/21/2006

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EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,755	Applicant(s) JANECZKO, RICHARD ADAM	
	Examiner Jason M. Sims	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a composition of nucleotides, classified in class 702, subclass 19.
- II. Claims 35-38, drawn to a composition of nucleotides, classified in class 702, subclass 19.
- III. Claims 5-19, drawn to a method of detecting the presence of a target nucleic acid, classified in class 702, subclass 19. If this group is elected, then the below summarized specie election is also required.
- IV. Claim 39-43 drawn to a method of detecting the presence of a target nucleic acid, classified in class 702, subclass 19.
- V. Claims 55-58, drawn to a method of detecting the presence of a target nucleic acid, classified in class 702, subclass 19.
- VI. Claims 63-66, drawn to a method of detecting the presence of a target nucleic acid, classified in class 702, subclass 19.
- VII. Claims 20-34, drawn to a method of analyzing a biological sample, classified in class 702, subclass 19. If this group is elected, then the below summarized specie election is also required.
- VIII. Claim 44-54, drawn to a method of analyzing a biological sample, classified in class 702, subclass 19. If this group is elected, then the below summarized specie election is also required.

- IX. Claims 59-62, drawn to a method of analyzing a biological sample, classified in class 702, subclass 19.
- X. Claims 67-70, drawn to a method of analyzing a biological sample, classified in class 702, subclass 19.

Inventions I, II, III, IV, V, VI, VII, VIII, IX, and X are directed to related subject matter of nucleic acids. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, groups I and II are drawn to a composition, but contain different method steps and compositions. For example, group I is just a composition, but group II involves mixing sequences to create a reaction mixture. Group III, IV, V, and VI are drawn to a method of detecting the presence of a target sequence. Groups III and IV involve a second oligonucleotide, which has a 3' portion based on different groups of sequences with different steps for substituting nucleotide bases. Group V involves a second target and third oligonucleotide sequence. Group VI also involves a second target and third oligonucleotide sequence, but has a 3' portion based on different groups of sequences with different steps for substituting nucleotide bases. Groups VII, VIII, IX, and X are drawn to a method of analyzing a biological sample for the presence of a mutation or polymorphism. Groups VII and VIII both involve a plurality of second oligonucleotides, which have a 3' portion based on different groups of sequences. Groups IX and X are drawn to a method of analyzing a biological

sample, but both involve a second target and third oligonucleotide sequence along with a second oligonucleotide, which has a 3' portion based on different groups of sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Nucleotide Sequence Selection, Required for All Groups I-X

Claims of each of the above inventive groups are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form, in particular a 3' portion of second oligonucleotide molecules. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Applicant is required to select no more than ONE of the individual sequences for a 3' portion of a said second oligonucleotide molecule for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

It is noted that this is a restriction requirement and NOT a specie election requirement.

Election of Species for Group III

This application contains claims directed to the following patentably distinct species: species of a Thermophilic organism: *Thermus aquaticus*, *Thermus flavus*, and *Thermus thermophilus*. The species are independent or distinct because they are distinct organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 5-19 are generic.

Election of Species for Group VII

This application contains claims directed to the following patentably distinct species: species of a Thermophilic organism: *Thermus aquaticus*, *Thermus flavus*, and *Thermus thermophilus*. The species are independent or distinct because they are distinct organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 20-34 are generic.

Election of Species for Group VIII

This application contains claims directed to the following patentably distinct species: species of a Thermophilic organism: *Thermus aquaticus*, *Thermus flavus*, and

Thermus thermophilus. The species are independent or distinct because they are distinct organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 44-54 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel can be reached via telephone (571)-272-0718.

Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)-272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ardin H. Marschel 3/16/06

**ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER**